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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,063	10/05/2001	John P. McKearn	CU-2562 RJS	4628

7590 08/15/2003  
Mr. James M. Warner  
Assistant General Counsel  
Pharmacia Corporation, Global Patent Department  
800 North Lindbergh Blvd.  
St. Louis, MO 63167

EXAMINER

GOLDBERG, JEROME D.

ART.UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/868,063	<b>Applicant(s)</b> MCKEARN ET AL.	
	<b>Examiner</b> Jerome D Goldberg	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-149 is/are pending in the application.
- 4a) Of the above claim(s) 4-41, 44-114, 116-123 and 126-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 42, 43, 115, 124 and 125 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1614

Claims 4-41, 44-114, 116-123 and 126-149 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Applicants traverse to this requirement is noted. The term "matrix metalloproteinase inhibitor" are defined on pages 45-95 of the specification which include hundreds of compounds including peptides. The term "cyclooxygenase-2-inhibitors" are define on pages 99-122 which include hundreds of compound of different heterocyclic structures and non-heterocyclic structures. (See pages 114 and 115) further, the claims are drawn to enhanced combination (vote paragraph one in paper no. 7, page 2). Therefore, the restriction requirement is herein made final.

Applicant is advised that should claim 115 be found allowable, claims 124 or 125 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 42, 43, 115, 124 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Seibert et al. Patent taken with the Santos et al. reference.

The instant application has an effective date of December 23, 1998. The Seibert et al. Patent has an effective date of October 14, 1997. The Santos et al. Reference has an effective date of 1997. The Seibert et al. Patent teaches applicants' celecoxib for treating neoplasia including lung cancer (see claims 1, 5 and 8; col.17 and 18) and basal cell carcinoma (see col.2, lines 47 and 48) in a subject in need thereof. The patent further teaches that the compound can be administered in conjunction with other antineoplastic agents (col.12, lines 46 and 47) including taxol (col.14, line 62) which is the same as paclitaxel in the instant claims.

The patent states that the administration can be "in a sequential manner" (col.15, lines 19 and 20) and "in a substantially simultaneous manner" (col.15, lines 22 and 23) which is the same as instant claims 2 and 3.

Art Unit: 1614

The Santos et al. Reference teaches applicants' thiomorpholinecarboxamide compound (AG3340) "was the most efficacious compd. Against Lewis lung carcinoma model, resulting in the complete cassation against primary tumor growth throughout the expt..." (first, AB, lines 14-16).

The reference and patent do not teach the combination together. However, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-neoplastic agents together for their additive effect since the three agents are taught for treating lung cancer. Clearly, the combination would be effective for treating lung cancer. There is no data of record showing that the claimed combination results in an enhanced effect. With regard to claim 43, two of the ingredients are effective against basel cell carcinoma.

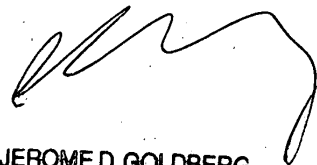
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd  
July 28, 2003

A handwritten signature in black ink, appearing to read 'J. Goldberg', with a long, sweeping horizontal stroke extending to the right.

JEROME D. GOLDBERG  
PRIMARY EXAMINER